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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,971	09/30/2003	Gary K. Michelson	101.0059-02000	4939

22882 7590 02/20/2007
MARTIN & FERRARO, LLP
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EXAMINER

WILLSE, DAVID H

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/674,971	MICHELSON, GARY K.	
	Examiner	Art Unit	
	Dave Willse	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12-7-06</u> | 6) <input type="checkbox"/> Other: _____ |

The Terminal Disclaimer filed on December 7, 2006, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. patent nos. 6,241,770 B1 and 6,485,517 B1 and any patents granted on U.S. application serial nos. 09/792,679 and 10/246,931 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The sub-step of drilling the opening (claims 35 and 46) is not believed to be supported in grandparent U.S. application serial no. 09/263,266.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-34, 36, 38, 41, 50, 51, 54, and 56 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tisserand, FR 2 727 003 A1: Derwent abstract; drawings. The grooves **1i**, the screws **2** and **3**, and the contours or planforms depicted in Figure 2 all define arcuate portions of upper and lower implant surfaces. Figure 3 illustrates an opening having been formed across the disc space and into portions of adjacent vertebral bodies to accommodate these geometries and the spongy grafts (Derwent title and abstract).

Claims 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tisserand, FR 2 727 003 A1. Regarding claim 35, the substep of drilling would have been immediately obvious to the ordinary practitioner in order to at least form holes for guiding the screws **2** and **3** into the respective vertebrae. Regarding claim 37, partially rotating the implant into the opening would have been obvious, if not inherent, in order to attain accurate alignment with the vertebral anatomy to which the implant conforms (Derwent abstract: lines 4-6) and in order to overcome any frictional or other impediments to full insertion.

Claims 29, 30, 33-36, 39-41, 44-47, and 50-57 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by *Sofamor Danek Laparoscopic Bone Dowel System: Laparoscopic Surgical Procedure* (1995). On the twelfth page, entitled "Bone Dowel Alternatives", the embodiment depicted on the bottom left possesses a non-linear trailing end generally conforming to at least one of the anterior and lateral aspects of the vertebral bodies, and at least a middle portion of the trailing end is seated on the peripheral rim of densely compacted bone of adjacent vertebral bodies. Regarding claims 33, 34, and others, attention is directed to the third page, lines 15-16, and to the second to last page, line 6. Regarding claims 40 and 41, the trailing end is

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asymmetrical about the mid-longitudinal axis and is symmetrical with respect to a transverse plane bisecting the implant.

Claims 31, 32, 37, 38, 42, 43, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Sofamor Danek Laparoscopic Bone Dowel System: Laparoscopic Surgical Procedure* (1995). Regarding claims 31, 32, and others, hollowing out to some extent the natural cavity of the dowel obtained from a femoral ring would have been obvious to the ordinary practitioner in order to inject bone morphogenetic protein or other substances so as to further facilitate fusion. Regarding claims 37, 38, and others, threaded dowels and other threaded fusion implants were quite common in the art at the time of the present invention and would have been obvious in order to enhance the initial fixation of the device and to circumvent the need for impact forces during the insertion step(s).

The Applicant's remarks have been considered but are deemed moot in view of the new grounds of rejection, necessitated by the revisions to claims 29 and 39. Therefore:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762 and who is generally available Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Dave Willse
Primary Examiner
Art Unit 3738